What is claimed is:

1. A device for delivering fluid to a patient, comprising:

A) an exit port assembly adapted to connect to a transcutaneous patient access tool;

B) a flow path extending from the exit port assembly; and

C) a flow condition sensor assembly including,

a resilient diaphragm having opposing first and second surfaces, with the first surface positioned against the flow path,

a chamber wall positioned adjacent the second surface of the diaphragm and defining a sensor chamber adjacent the second surface of the diaphragm, and

at least one sensor arranged to provide a threshold signal when the second surface of the diaphragm expands into the chamber in response to at least one predetermined fluid flow condition occurring in the flow path.

2. A device according to Claim 1, wherein the predetermined fluid flow condition comprises one of an occlusion in the flow path, an inadequate flow of fluid in the flow path, and an adequate flow of fluid in the flow path.

3. A device according to Claim 1, wherein the flow path includes a reservoir and the flow condition sensor assembly is positioned at an end of the reservoir.

4. A device according to Claim 1, wherein the flow path includes a reservoir and a passageway providing fluid communication between the reservoir and the exit port assembly, and the flow condition sensor assembly is positioned against the passageway.

5. A device according to Claim 1, wherein the sensor comprises a switch positioned within the chamber such that the second surface of the diaphragm closes the switch upon expanding into the chamber in response to the predetermined fluid flow condition within the flow path.

6. A device according to Claim 1, wherein the sensor is responsive to one of contact, pressure, light, magnetism, strain, and density.

7. A device according to Claim 1, wherein the sensor is positioned on a portion of the chamber wall furthest from the flow path and the enclosed chamber has a predetermined volume.

8. A device according to Claim 1, wherein the sensor comprises a circuit having a lead positioned on the second surface of the diaphragm and a lead positioned on the chamber wall such that the leads come together and close the circuit when the second surface of the diaphragm expands into the chamber in response to the predetermined fluid flow condition.

9. A device according to Claim 1, wherein the sensor comprises a circuit having leads positioned on the chamber wall and a conductive layer positioned on the second surface of the diaphragm such that the conductive layer contacts the leads to close the circuit when the second surface of the diaphragm expands into the chamber in response to the predetermined fluid flow condition.

10. A device according to Claim 1, wherein the flow condition sensor assembly further comprises at least two laminated layers and the diaphragm is positioned between two of the layers.

11. A device according to Claim 10, wherein the at least two laminated layers comprise:

a first layer;

a second layer received against the first layer, the second and the first layers including at least one groove defining a passageway of the flow path, the second layer including an opening in fluid communication with the passageway, and wherein the resilient diaphragm is received on the second layer covering the opening; and

a third layer received over the diaphragm on the second layer, the third layer including the chamber wall defining the chamber over the diaphragm and in alignment with the opening of the second layer.

12. A device according to Claim 11, wherein one of the second and the third layers defines a recess receiving the diaphragm, and wherein the recess has a depth about equal to a thickness of the diaphragm such that the diaphragm is secured in a substantially fluid-tight manner between the second and the third layers.

13. A device according to Claim 12, wherein a length and a width of the recess are greater than a length and a width of the diaphragm.

14. A device according to Claim 1, wherein the diaphragm comprises a thin, flat piece of flexible and resilient material.

15. A device according to Claim 1, wherein the sensor chamber has a predetermined volume.

16. A device according to Claim 1, wherein the flow condition sensor assembly includes an alarm connected to the sensor.

17. A device according to Claim 16, wherein the alarm comprises an audible alarm.

18. A device according to Claim 16, wherein the alarm comprises a visual alarm.

19. A device according to Claim 1, further comprising a processor connected to the sensor of the sensor assembly.

20. A device according to Claim 19, further comprising an alarm connected to the processor.

21. A device according to Claim 20, wherein the alarm comprises an audible alarm.

22. A device according to Claim 20, wherein the alarm comprises a visual alarm.

23. A device according to Claim 20, wherein the processor is programmed to activate the alarm upon receiving the threshold signal from the sensor.

24. A device according to Claim 20, wherein the processor is programmed to activate the alarm upon receiving the threshold signal from the sensor for more than a predetermined period.

25. A device according to Claim 20, wherein the processor is programmed to activate the alarm upon receiving the threshold signal from the sensor for less than a predetermined period.

26. A device according to Claim 19, wherein the sensor provides an analog signal and the processor include an analog-to-digital converter for converting the analog single of the sensor into a digital signal.

27. A device according to Claim 19, wherein the processor is programmed to provide a signal indicative of an undesired flow condition upon receiving the threshold signal from the sensor.

28. A device according to Claim 19, wherein the processor is programmed to provide a signal indicative of an occluded flow condition upon receiving the threshold signal from the sensor for more than a predetermined period.

29. A device according to Claim 19, wherein the processor is programmed to provide a signal indicative of a low flow condition upon receiving the threshold signal from the sensor for less than a predetermined period.

30. A device according to Claim 19, wherein the processor is programmed to receive the threshold signal from the sensor when the device is primed.

31. A device according to Claim 1, wherein the flow path includes a reservoir containing a therapeutic fluid.

32. A device according to Claim 31, wherein the therapeutic fluid is insulin.

33. A device according to Claim 31, further comprising a fill port connected to the reservoir.

34. A device according to Claim 31, wherein the reservoir is pressurized.

35. A device according to Claim 1, wherein the exit port assembly includes a transcutaneous patient access tool.

36. A device according to Claim 35, wherein the transcutaneous patient access tool comprises a needle.

37. A device according to Claim 1, wherein a combined volume of the exit port assembly and the flow path is fixed and predetermined.

38. A device according to Claim 1, wherein possible expansion of a combined volume of the exit port assembly and the flow path is relatively small compared with the volume of the sensor chamber.

39. A device according to Claim 1, further comprising:

a dispenser for causing fluid through the flow path to the exit port assembly;

a local processor connected to the dispenser and programmed to cause fluid flow to the exit port assembly based upon flow instructions;

a wireless receiver connected to the local processor for receiving flow instructions from a separate, remote control device and delivering the flow instructions to the local processor; and

a housing containing the flow path, the exit port assembly, the dispenser, the local processor, and the wireless receiver, wherein the housing is free of user input components for providing flow instructions to the local processor.

40. A system including a fluid delivery device according to Claim 39, and further comprising a remote control device separate from the fluid delivery device and including:

a remote processor;

user interface components connected to the remote processor for allowing a user to provide flow instructions to the remote processor; and

a transmitter connected to the remote processor for transmitting the flow instructions to the receiver of the fluid delivery device.

41. A device according to Claim 1, further comprising:

a dispenser for causing fluid through the flow path to the exit port assembly;

a local processor connected to the dispenser and programmed to cause fluid flow to the exit port assembly based upon flow instructions, and further programmed to provide flow information;

a wireless transmitter connected to the local processor for transmitting the flow information from the local processor to a separate, remote control device; and

a housing containing the flow path, the exit port assembly, the dispenser, the local processor, and the wireless transmitter, wherein the housing is free of user output components for providing the flow information from the local processor to a user.

42. A system including a fluid delivery device according to Claim 41 and further comprising a remote control device separate from the fluid delivery device and including:

a remote processor;

user output components connected to the remote processor for allowing a user to receive flow information; and

a receiver connected to the remote processor for receiving the flow information from the transmitter of the fluid delivery device.

43. A system according to Claim 42, wherein the remote control device includes an alarm connected to the remote processor.

44. A device according to Claim 1, wherein the sensor assembly includes multiple sensor chambers positioned against the second surface of the diaphragm.

45. A device according to Claim 44, wherein the sensor assembly includes at least one of the sensors in each chamber.

46. A device according to Claim 44, wherein each of the sensor chambers of the sensor assembly has a predetermined volume.

47. A device according to Claim 1, wherein the sensor assembly includes a second diaphragm positioned against the flow path.

48. A device according to Claim 47, wherein the sensor assembly includes a second chamber assembly positioned against the second diaphragm.

49. A device according to Claim 48, wherein the sensor assembly includes a second sensor arranged to provide a threshold signal when the second diaphragm expands into the second chamber.

50. A device according to Claim 1, wherein the sensor comprises a path way extending through the sensor chamber, and an optical transmitter and an optical receiver positioned at opposite ends of the path way.

51. A device for delivering fluid to a patient, comprising:

A) a flow path extending from the exit port assembly;

B) a flow condition sensor assembly including,

a resilient diaphragm having opposing first and second surfaces, with the first surface positioned against the flow path,

a chamber wall positioned adjacent the second surface of the diaphragm and defining a sensor chamber adjacent the second surface of the diaphragm, and

at least one sensor arranged to provide a threshold signal when the second surface of the diaphragm expands into the chamber by a predetermined amount; and

C) a processor connected to the sensor and programmed to provide a signal indicative of an undesired flow condition upon receiving the threshold signal from the sensor for more than a predetermined maximum period or for less than a predetermined minimum period.

52. A device according to Claim 51, further comprising an alarm connected to the processor and adapted to be activated upon the processor providing a signal indicative of an undesired flow condition.

53. A device according to Claim 52, wherein the alarm comprises an audible alarm.

54. A device according to Claim 52, wherein the alarm comprises a visual alarm.

55. A device according to Claim 51, wherein the sensor provides an analog signal and the processor include an analog-to-digital converter for converting the analog single of the sensor into a digital signal.

56. A device according to Claim 51, wherein the flow path includes a reservoir and the flow condition sensor assembly is positioned at an end of the reservoir.

57. A device according to Claim 51, wherein the flow path includes a reservoir and a passageway providing fluid communication between the reservoir and an exit port assembly, and the flow condition sensor assembly is positioned against the passageway.

58. A device according to Claim 51, wherein the sensor comprises a switch positioned within the chamber such that the second surface of the diaphragm closes the switch upon expanding into the chamber by the predetermined amount.

59. A device according to Claim 51, wherein the sensor is responsive to one of contact, pressure, light, magnetic, strain, and density.

60. A device according to Claim 51, wherein the sensor is positioned on a portion of the chamber wall furthest from the flow path and the enclosed chamber has a predetermined volume.

61. A device according to Claim 51, wherein the sensor comprises a circuit having a lead positioned on the second surface of the diaphragm and a lead positioned on the chamber wall such that the leads come together and close the circuit when the second surface of the diaphragm expands into the chamber by the predetermined amount.

62. A device according to Claim 51, wherein the sensor comprises a circuit having leads positioned on the chamber wall and a conductive layer positioned on the second surface of the diaphragm such that the conductive layer contacts the leads to close the circuit when the second surface of the diaphragm expands into the chamber in response to the predetermined fluid flow condition.

63. A device according to Claim 51, wherein the flow condition sensor assembly further comprises at least two laminated layers and the diaphragm is positioned between two of the layers.

64. A device according to Claim 63, wherein the at least two laminated layers comprise:

a first layer;

a second layer received against the first layer, the second and the first layers including at least one groove defining a passageway of the flow path, the second layer including an opening in fluid communication with the passageway, and wherein the resilient diaphragm is received on the second layer covering the opening; and

a third layer received over the diaphragm on the second layer, the third layer including the chamber wall defining the chamber over the diaphragm and in alignment with the opening of the second layer.

65. A device according to Claim 64, wherein one of the second and the third layers defines a recess receiving the diaphragm, and wherein the recess has a depth about equal to a thickness of the diaphragm such that the diaphragm is secured in a substantially fluid-tight manner between the second and the third layers.

66. A device according to Claim 65, wherein a length and a width of the recess are greater than a length and a width of the diaphragm.

67. A device according to Claim 51, wherein the diaphragm comprises a thin, flat piece of flexible and resilient material.

68. A device according to Claim 51, wherein the sensor chamber has a predetermined volume.

69. A device according to Claim 51, wherein the flow path includes a reservoir containing a therapeutic fluid.

70. A device according to Claim 69, wherein the therapeutic fluid is insulin.

71. A device according to Claim 69, wherein the reservoir is pressurized.

72. A device according to Claim 51, wherein the flow path includes an exit port assembly includes a transcutaneous patient access tool.

73. A device according to Claim 72, wherein the transcutaneous patient access tool comprises a needle.

74. A device according to Claim 51, wherein a combined volume of the flow path is substantially fixed and predetermined.

75. A device according to Claim 51, further comprising:

a dispenser for causing fluid to flow through the flow path;

a local processor connected to the dispenser and programmed to cause fluid flow based upon flow instructions;

a wireless receiver connected to the local processor for receiving flow instructions from a separate, remote control device and delivering the flow instructions to the local processor; and

a housing containing the flow path, the dispenser, the local processor, and the wireless receiver, wherein the housing is free of user input components for providing flow instructions to the local processor.

76. A system including a fluid delivery device according to Claim 75, and further comprising a remote control device separate from the fluid delivery device and including:

a remote processor;

user interface components connected to the remote processor for allowing a user to provide flow instructions to the remote processor; and

a transmitter connected to the remote processor for transmitting the flow instructions to the receiver of the fluid delivery device.

77. A device according to Claim 51, further comprising:

a dispenser for causing fluid to flow through the flow path;

a local processor connected to the dispenser and programmed to cause fluid flow through the flow path based upon flow instructions, and further programmed to provide flow information;

a wireless transmitter connected to the local processor for transmitting the flow information from the local processor to a separate, remote control device; and

a housing containing the flow path, the dispenser, the local processor, and the wireless transmitter, wherein the housing is free of user output components for providing the flow information from the local processor to a user.

78. A system including a fluid delivery device according to Claim 77 and further comprising a remote control device separate from the fluid delivery device and including:

a remote processor;

user output components connected to the remote processor for allowing a user to receive flow information; and

a receiver connected to the remote processor for receiving the flow information from the transmitter of the fluid delivery device.

79. A device according to Claim 51, wherein the sensor assembly includes multiple sensor chambers positioned against the second surface of the diaphragm.

80. A device according to Claim 79, wherein the sensor assembly includes at least one of the sensors in each chamber.

81. A device according to Claim 79, wherein each of the sensor chambers of the sensor assembly has a predetermined volume.

82. A device according to Claim 51, wherein the sensor assembly includes a second diaphragm positioned against the flow path.

83. A device according to Claim 82, wherein the sensor assembly includes a second chamber assembly positioned against the second diaphragm.

84. A device according to Claim 83, wherein the sensor assembly includes a second sensor arranged to provide a threshold signal when the second diaphragm expands into the second chamber.

85. A device according to Claim 51, wherein the sensor comprises a path way extending through the sensor chamber, and an optical transmitter and an optical receiver positioned at opposite ends of the path way.

86. A device according to Claim 30, wherein the processor is programmed to stop operation upon receiving the threshold signal from the sensor.

87. A device according to Claim 30, wherein the processor is programmed to stop operation upon receiving the threshold signal from the sensor for more than a predetermined period.

88. A device according to Claim 30, wherein the processor is programmed to stop operation upon receiving the threshold signal from the sensor for less than a predetermined period.

89. A method for determining a fluid flow condition in a flow path, comprising:

positioning a first side of a resilient diaphragm against the flow path;

positioning a chamber wall adjacent a second surface of the diaphragm, the chamber wall defining a sensor chamber adjacent the second surface of the diaphragm;

providing a threshold signal when the second surface of the diaphragm expands into the chamber by a predetermined amount;

timing the duration of the threshold signal; and

providing a signal indicative of a predetermined flow condition if the duration of the threshold signal is greater than a predetermined maximum period or less than a predetermined minimum period.

90. A method according to claim 89, further comprising activating an alarm upon providing a signal indicative of a predetermined flow condition.

91. A method according to claim 89, further comprising providing the sensor chamber with a predetermined volume.

92. A method according to claim 89, further comprising providing the sensor chamber with a predetermined volume and providing a threshold signal when the second surface of the diaphragm contacts the chamber wall.

93. A method according to claim 89, further comprising providing the flow path with a substantially fixed and predetermined volume.

94. A method according to claim 89, wherein the predetermined fluid flow condition comprises one of an occlusion in the flow path, and an inadequate flow of fluid in the flow path.

95. A method according to claim 89, further comprising:

closing the flow path;

causing a volume of fluid at least equal to a volume of the sensor chamber to flow into the fluid path; and

providing a signal indicative of an occlusion test failure if the duration of the threshold signal is less than the predetermined maximum period.

96. A method according to claim 95, further comprising positioning a second diaphragm against the flow path.

97. A method according to claim 89, further comprising:

providing pulsitile flow of fluid within the flow path; and

monitoring the threshold signals between pulses of fluid.